

Remarks

Favorable reconsideration of this application is requested. Claims 1, 3, 4, 8, 15, and 19 are canceled without prejudice or disclaimer. Claims 20-25 are added. Claim 20 is supported, for example at page 9, lines 23-31 and page 12, line 23 to page 13, line 12. Claim 21 is supported, for example at page 4, lines 27-30. Claims 22, 23, and 25 are respectively supported by original claims 3, 4, and 8. Claim 24 is supported, for example at page 9, lines 23-31. No new matter has been added, and claims 20-25 reflect the invention originally elected.

Claim Rejections- 35 U.S.C. 103

Claims 1, 3, 4, 8, 15, and 19 under 35 U.S.C. § 103(a) as being unpatentable over Upadhyay et al. (US 6,251,383) in view of De Souza et al. (US 2002/0142055). The rejection is rendered moot, as these claims have been canceled. Applicants do not concede the correctness of the rejection.

New Claims 20-25

Claims 20-25 are patentable over the cited references of record. Claim 20 is directed to a method for the treatment of a renal disorder in a mammal in need thereof, the renal disorder is a chronic recurrent urinary tract infection, the method comprises administering to the mammal a composition of a standardized extract of *Tinospora cordifolia* as an immunoadjuvant in a dosage of 20 to 80 mg/kg body weight per day, in conjunction with an antibacterial agent over a period ranging from 20 days to three months.

In the final Office Action mailed August 11, 2010, the previous claims 1, 3, 4, 8, 15, and 19 were alleged as obvious over Upadhyay et al. (US 6,251,383) in view of De Souza et al. (US 2002/0142055). In the rejection, it was stated Upadhyay et al. establishes that plants of *Tinospora* species such as *Tinospora cordifolia* are known in traditional Indian medicine for the treatment of urinary tract infections, and that De Souza et al. teaches that the standardized extract of *Tinospora cordifolia* is known to be co-administered with antibacterial agents such as penicillin. On this basis, the conclusion was made in the Office Action that urinary tract infections occur due to relapsing bacterial infections, and it would be obvious to a person having ordinary skill in the art to use penicillin with the extract of *Tinospora cordifolia* for the treatment of recurrent urinary tract infections.

Applicants do not concede the correctness of the reasoning in the Office Action. However, it is respectfully submitted that present claims 20-25 are patentable over the cited references. Particularly, claim 20 would not be obvious over the combined teachings of the prior art documents, because none of the prior art documents, either alone or in combination, teaches the dosage regimen for administration of the standardized extract of *Tinospora cordifolia* for the treatment of recurrent urinary tract infections over the specified time period. Indeed, the dosage and the duration of the treatment as recited in claim 20 are absent from the references cited, namely Upadhyay et al. and De Souza et al. Consequently, claim 20 does not follow from the references cited.

Furthermore, Applicants have demonstrated the efficacy of the instantly claimed method of treatment through the recitation of a case study. The patients in the case study were treated for recurrent UTI by administering a composition containing the standardized extract of *Tinospora cordifolia* in specified amount as an adjunct with antibacterial therapy. The results show a complete resolution over a one year observation period with no further episodes of UTI. In this regard, a particular reference is made to the data presented in Table 3 and the description on pages 12 to 13 of Applicants' specification. Thus, even if the references cited, i.e. Upadhyay et al. and De Souza et al. could be combined, which Applicants do not concede, the references fail to teach the treatment regimen and there is no reason that one would expect to arrive at the effects that may be obtained by Applicants' invention.

For at least the foregoing reasons, claims 20-25 are patentable.

In view of the aforementioned amendments and remarks, Applicants respectfully submit that the claims as currently presented are in allowable condition and a notice of allowance is respectfully requested.



Dated: October 29, 2010

Respectfully submitted,

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